UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,349	08/01/2003	Donald A. Sargent	ST8725US	3719
22203 7590 04/20/2007 KUSNER & JAFFE			EXAMINER	
HIGHLAND P	LACE SUITE 310		CHORBAJI, MONZER R	
6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143			ART UNIT	PAPER NUMBER
			1744	
			·	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		04/20/2007	PAPER	

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

·						
	Application No.	Applicant(s)				
Office A 44' O	10/633,349	SARGENT ET AL.				
Office Action Summary	Examiner	Art Unit				
·	MONZER R. CHORBAJI	1744				
The MAILING DATE of this communication ap Period for Reply	opears on the cover sheet with the	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING I  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the maili earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATIO .136(a). In no event, however, may a reply be to d will apply and will expire SIX (6) MONTHS fron the, cause the application to become ABANDON	DN. imely filed  the mailing date of this communication. ED (35 U.S.C. § 133).				
Status	•					
1) Responsive to communication(s) filed on 29.	January 2007.					
	<u> </u>					
3) Since this application is in condition for allow	· <u> </u>					
closed in accordance with the practice under	Ex parte Quayle; 1935 C.D. 11, 4	153 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-13 and 16-24</u> is/are pending in the	application					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5)⊠ Claim(s) <u>24</u> is/are allowed.						
6)⊠ Claim(s) <u>1-13 and 16-23</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/	or election requirement.					
Application Papers						
9) The specification is objected to by the Examin	ner.					
10)⊠ The drawing(s) filed on <u>01 August 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the	e drawing(s) be held in abeyance. Se	ee 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the corre		•				
11) The oath or declaration is objected to by the E	Examiner. Note the attached Offic	e Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of:	n priority under 35 U.S.C. § 119(a	a)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No.						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
	application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.						
•						
		•				
Attachment(s)						
Notice of References Cited (PTO-892)	4) Interview Summar					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Patent Application					
Paper No(s)/Mail Date	6) Other:	TF"TT"				

Art Unit: 1744

### **DETAILED ACTION**

This non-final is in response to the RCE/Amendment received on 01/29/2007

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-13 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky (U.S.P.N. 5,552,115) in view of Bassett (U.S.P.N. 957,029).

Page 3

Regarding claims 1, 7 and 12, Malchesky teaches the following: a container (figure 4:C) with a generally cup-shaped tray that includes a bottom wall and a continuous side wall, bottom and side walls defining a cavity (figure 4:62, 60, col.6, lines 64-67 and col.7, lines 1-6), a lid attachable to the tray, a fluid inlet in the tray communicating with the cavity (figure 4:72), a fluid outlet in the tray communicating with the cavity (figure 4:70) where each of the inlet and the outlet has a valve assembly (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves moves into an open position for allowing liquid sterilant to enter and exit the tray and when the tray is removed from the decontamination chamber the valves moves into a closing position for sealing the container (col.7, lines 5-6, lines 26-30) and a circulation system (col.6, lines 24-27) such that the cavity is in communication with the circulation system through the valves when the container is placed in the decontamination chamber. However, Malchesky does not specifically teach using a flexible valve element being formed as a one-piece and having a movable part and a fixed part in the container that is moved by a mechanical actuator in the decontamination chamber such that the valve element is disposed away from the surface toward the cavity when in open position and the valve element engages the surface when in closed position. Bassett's flexible valve element being formed as a one-piece (figure 1:9 and 5) and having a movable part (figure 1:9) and a

Art Unit: 1744

fixed part (figure 1:5) in the container (figure 1:1) that is moved by a mechanical actuator (figure 1:18) such that the valve element is disposed away from the surface toward the cavity (figure 1:9) when in open position and the valve element engages the surface when in closed position (figure 1:9). In addition, Bassett connects both portions (figure 1:9 and 5) of the flexible one-piece valve element by a plurality of radially extending arms (figure 1:6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Malchesky's check valves with Bassett's movable actuated valves for the benefit of obtaining a water-tight connection between the valve and its seat as disclosed on page 2, left column, lines 28-31 of Bassett.

Regarding claims 2-3, 5-6, 9, 11, 13, 19-20 and 22-23, Malchesky discloses flexible valve elements that close and open based on pressure differentials (col.7, lines 25-28) formed of a resilient flexible material (col.7, lines 24-26) where a tray includes multiple inlets and an outlet (figure 4:72 and 70) such that each inlet and outlet includes a check valve (figure 4:74) that opens and closes independently of other valves. One of ordinary skill in the art would recognize that Malchesky's check valve (figure 4:74) has a fixed portion for anchoring the valve and another movable portion that moves between closed and opened states. In addition, Malchesky teaches the following: a circulation system (col.6, lines 24-27) with a first fluid inlet line (figure 2:32) and a fluid outlet line (figure 3:36) that communicates with the first fluid inlet port (figure 4:72) and the fluid outlet port (figure 4:70) of a container (figure 4 C) when the container is disposed in the decontamination chamber (col.7, lines 5-6, lines 26-30), fluid inlet (for example, figure

Art Unit: 1744

4:72) is in communication with a nozzle (figure 4:78) within the container, fluid inlet is in communication with connectors (figure 4:78) connected with medical instruments (figure 5:78 and 76), a microbial liquid decontamination solution (col.5, lines 53-55) and an essentially closed loop circulation system for circulating the liquid sterilant (col.6, lines 24-27).

Regarding claims 4, 8, 10, 16-18 and 21, Malchesky discloses flexible valve elements that close and open based on pressure differentials (col.7, lines 25-28) formed of a resilient flexible material (col.7, lines 24-26) where a tray includes multiple inlets and an outlet (figure 4.72 and 70) such that each inlet and outlet includes a check valve (figure 4:74). One of ordinary skill in the art would recognize that Malchesky's check valve (figure 4:74) has a fixed portion for anchoring the valve and another movable portion that moves between closed and opened states; yet, Malchesky does not specifically teach a movable actuator element for opening and closing his valves. Bassett discloses a flexible valve element being formed as a one-piece (figure 1:9 and 5) and having a movable part (figure 1:9) and a fixed part (figure 1:5) in the container (figure 1:1) that is moved by a mechanical actuator (figure 1:18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Malchesky's check valves with Bassett's movable actuated valves for the benefit of obtaining a water-tight connection between the valve and its seat as disclosed on page 2, left column, lines 28-31 of Bassett.

## Allowable Subject Matter

**5.** Claim 24 is allowed.

Art Unit: 1744

# Response to Arguments

**6.** Applicant's arguments with respect to claims 1-13 and 16-23 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

- 7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Snyder et al (U.S.P.N. 3,267,491) and Clifford (U.S.P.N. 1,247,643) teach one-piece valve assembly having a first movable portion and a second fixed portion where the portions are connected to each other with plurality of radially extending arms.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.
- **9.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER